

Remarks

In response to the Final Office Action mailed 25 June 2009 the applicant herein submits the following amendments and remarks.

The applicant provides the following submissions with this communication: 1) Transmittal Form (PTO/SB/21); 2) Petition for 3 Month Extension of Time under 37 C.F.R. §1.136(a) (PTO/SB/22); 3) Certificate of Mailing (PTO/SB/92); 4) Request for Continued Examination (RCE) Transmittal (PTO/SB/30); and 5) applicant's substantive Amendment and Response (7) pages.

The Final Office Action set a three-month Shortened Statutory Period extendable until 25 September 2009 under 37 C.F.R. §1.136(a) for submission of a responsive communication. Applicant's response is timely in view of the three (3) month Petition for Extension and payment of extension fee pursuant to 37 C.F.R. §1.17(a)(3). The applicant also herein submits a Request for Continued Examination. The applicant authorizes the Commissioner to charge, or credit any overpayment associated/necessary with this communication to U.S.P.T.O. Deposit Account No.: 50-0244.

Claim 18 is currently pending. The applicant has amended claim 18 in order to advance prosecution and his business interests without acquiescing to the Examiner's arguments and while reserving the right to prosecute claims directed to any canceled or amended subject matter in the future. The claim amendments are fully supported by the specification as originally filed and do not add new matter. For example, Specification paragraphs 80-91 describe the immunological affects of administration of the inventive compositions on test subjects. Included within these paragraphs are several Tables that provide data quantifying the serum IgG response and serum bactericidal antibody responses. The remaining amendments to claim 18 have been submitted to correct antecedent basis issues pointed out by the Examiner.

In view of the applicant's last submission the Examiner withdrew (or stated were moot) various previously entered rejections. (25 June 2009 Final Office Action, ¶¶5-14). The applicant gratefully acknowledges the withdrawal of these rejections.

Nevertheless, the instant Final Office Action set forth several new rejections as follows:

1. Claim 18 stands rejected under 35 U.S.C. §112, ¶1, as containing new subject matter (25 June 2009 Final Office Action ¶15);

2. Claim 18-33 stands rejected under 35 U.S.C. §112, ¶ 2, as being indefinite (25 June 2009 Final Office Action ¶¶16-17); and
3. Claim 18 stands rejected under 35 U.S.C. §103(a) over Beuvery *et al.* (Infect. Immun., 41:609-617 [1983]) in view of McMaster (U.S. 6,146,902), Perkins *et al.* (J. Amer. Med. Assoc., 283(21):2842-2843 [2000], and Cadoz *et al.*, (Vaccine, 3:340-342 [1985] *Abstract*) (25 June 2009 Final Office Action ¶¶18-19).

The amendments and remarks submitted herein are intended to be responsive to the Examiner's concerns, to advance the prosecution of the present application, and to place the application in condition for immediate allowance. Reexamination and reconsideration of the pending claims as amended herein is respectfully requested.

Rejection 1: Alleged New Matter in Claim 18

Claim 18 stands rejected as allegedly containing new subject matter. Applicant must respectfully disagree with the Examiner's arguments. Nevertheless, applicant believes that the above-mentioned amendments made to claim 18, for reasons other than addressing the instant rejection, render this rejection moot. Currently amended claim 18 recites one embodiment of the present invention. The embodiment recited herein was specifically found by the Examiner to present allowable subject matter in regard to the requirements of 5 U.S.C. §112, ¶1 and the new matter restrictions. Applicant respectfully requests this rejection be withdrawn.

Rejection 2: The Indefiniteness Rejection over Claim 18

Claim 18 stands rejected as being indefinite. Applicant must respectfully disagree with the Examiner's arguments. Nevertheless, applicant believes that the above-mentioned amendments made to claim 18, for reasons other than addressing the instant rejection, render this rejection moot. Applicant gratefully acknowledges the Examiner's suggestions for overcoming the indefiniteness rejections. Applicant respectfully requests this rejection be withdrawn.

Rejection 3: The Obviousness Rejection over Claim 18

Claim 18 stands rejected as being obvious over Beuvery *et al.* (of record) in view of McMaster (of record), Perkins *et al.* (of record), and Cadoz *et al.*

The Examiner states that Cadoz *et al.* teach a "tetraivalent vaccine comprising

capsular polysaccharides of serogroups A, C, Y and W-135” Respectfully, the present citation of the Cadoz reference, at best, might fractionally add to the numerous existing combinations of the references already made of record and previously used by the Examiner in obviousness rejections especially in view of the Examiner’s previous arguments of record concerning the U.S. FDA approved and marketed MENOMUNE® (tetravalent A, C, Y, and W-135 meningococcal polysaccharide vaccine) product teach a tetravalent (A, C, Y, and W-135) polysaccharide vaccine. The present obviousness rejection is the sole remaining art-based rejection in the prosecution to date. Thus, the applicant has already overcome various obviousness rejections over combinations of: 1) Ambrosch; 2) Andre; 3) Avendano; 4) Beuvery; 5) Chong; 6) Constantino; 7) Fusco; 8) Granoff; 9) Jennings; 10) Levin; 11) Lindberg; 12) Linguppa; 13) McMaster; 14) Morley; 15) Perkins; 16) Petre; and 17) Scheerson. The applicant respectfully notes that the shortcomings of the Beuvery *et al.*, in view of McMaster and Perkins *et al.* combination of references in previous obviousness rejection(s) have already been discussed. Nevertheless, the applicant now turns to the latest combination of these references with the instant addition of the Cadoz *et al.* reference.

The test of obviousness was set forth by the U.S. Supreme Court in the *Graham v. John Deere Co.*, decision. (*Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966)). *Graham* set out four key inquiries that must be considered in determining obviousness under §103: 1) determine the scope and content of the prior art; 2) ascertain the differences between the prior art and the claims at issue; 3) resolve the level of ordinary skill in the pertinent art; and 4) weigh any relevant secondary considerations of nonobviousness. All *Graham* factors must be considered and each piece of the applicant’s evidence of nonobviousness going to the factors must be weighed.

Graham explicitly cautions (*i.e.*, the lower courts, the Patent Office, and examiners) that standards are needed during examination “to ‘guard against slipping into use of hindsight,’ and to resist the temptation to read into the prior art the teachings of the invention in issue.” (*Graham*, p. 36) (quoting *Monroe Auto Equip. Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1964)). As has been stated by others, the TSM provides the guard. The prohibition against the use of hindsight during obviousness examinations is relevant to all obviousness examinations.

Applicant believes that the Examiner continues to resist giving the full weight and due that should be accorded to the totality of evidence pertaining to the *Graham* factors which the applicant has submitted. (*KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (U.S. Apr. 30, 2007)).

Obviousness examination must be undertaken against the scope and content of the prior art at the time of invention. The scope and content of the prior art must be established by objective evidence submitted on the part of both Examiner and the applicant. Applicant believes that his remarks and objective evidence (*i.e.*, 3rd party references showing the scope and content of the art, the differences between the claimed invention and the prior art; and the level of ordinary skill in the prior art at the time of invention) submitted in his previous papers continues to be disregarded. Applicant's belief is based on the complete absence of any discussion or rebuttal of each of the applicant's various third-party citations and his remarks concerning these citations. Applicant's attempt to properly portray the uncertainty and unpredictability of the art at the time of invention through this evidence have not been properly considered, and indeed, apparently ignored throughout the history of this prosecution.

Finally, the instant Final Office Action is again completely silent on weighing the applicant's objective evidence of Secondary Considerations negating and/or overcoming the establishment of a *prima facie* case of obviousness made previously by the applicant. While the applicant must very strongly assert that a *prima facie* case of obviousness has not been established, the Secondary Consideration evidence presented related to the MENACTRA® vaccine when viewed under the framework set forth by the U.S. Supreme Court in the landmark *Graham v. John Deere Co.*, decision strongly points to the non-obviousness of the presently claimed invention.

In view of the remarks previously made of record and those presented herein, the applicant must respectfully submit that the Examiner has not established the *prima facie* obviousness of the pending claims. The pending obviousness rejections should be withdrawn without further delay or prejudice to the applicant's interests.

Respectfully submitted,

By: 28 DEC 2009
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